IRB MED MODIFICATION FORM

Modification

Please note that if these changes involve changes to Radiation Safety or Biosafety, the IRB will hold its approval until Radiation Safety or Biosafety forwards its approval to the IRB. IMPORTANT Cancer Institute Scientific Review Committee (SRC) requirements: For cancer-related studies - All changes to the protocol's study design and/or accrual numbers must be submitted to the SRC to determine if re-review is required prior to continuing enrollment. See <u>http://cancer.stanford.edu/trials/srctop.html</u> for more information.

1. Summarize your proposed changes.

Proceed to the appropriate section(s), and make your changes. Make necessary changes in Consent/Assent Form(s) and HIPAA, using "track changes" so that reviewers can see what was changed, when applicable

2. Indicate Level of Risk

(If level of risk has changed, please update the section 'Risks' in the protocol information.)

O Increase O No Change O Decrease

3. Update the Conflict of Interest (COI) section if any changes in COI have been made since the last protocol submission.

O Yes O No Is there a change in the conflicting interest status of this protocol?

If yes, explain the change in the potential conflict of interest.

4. Approval Includes

List of Sections (and questions) that have been changed/modified